

I. REMARKS:

A. Status of the Claims

The application was originally filed with claims 1-4. Claim 5 was added in a response to Office Action filed on January 28, 2005. No claims are amended, added or canceled herein. Therefore, claims 1-5 are currently pending.

B. The Claims are Patentable Under 35 U.S.C. §112, First Paragraph

The Action rejects claims 1 and 2 under §112, first paragraph as failing to comply with the written description requirement. In further defining the rejection, the Action states that the “claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.” The Action argues that the claim language reciting the “treatment of ... RP and other hereditary degenerative retinal disease” requires treatment of unspecified disease and no evidence indicates that the treatable disease was known to application. Application respectfully traverses.

The first paragraph of section 112 of the patent laws requires that a patentee disclose in the patent sufficient information to put the public in possession of the invention and to enable those skilled in the art to make and use the invention. (See MPEP §2162, p. 2100-171, Aug. 2005). “To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.” (MPEP §2163, 2100-172, Aug. 2005). An inventor may show that he or she was in possession of the invention by describing the claimed

invention using such descriptive means as words, figures, structures, diagrams and formulas that fully set forth the claimed invention. (MPEP §2163, p. 2100-172-173, Aug. 2005).

To determine whether the claims are adequately described in the specification such that the skilled artisan would believe that the inventor was in possession of the claimed invention, one must start by reviewing each claim as a whole. (See MPEP § 2163 II.A.1., p. 2100-176, Aug. 2005). In the present case, claim 1 is directed to “A method for treating persons suffering from acute or chronic degenerative conditions or diseases of the eye which comprises administering a pharmaceutically effective amount of a histone deacetylase inhibitor...” Claim 1 includes a list of potential histone deacetylase inhibitors for use in the claimed methods. Claim 2 provides a list of conditions or diseases to be treated by the methods of the invention. The MPEP emphasizes that “the lack of definitions or details for well-established terms or procedures should not be the basis of a rejection under” §112, paragraph 1 for lack of adequate written description (MPEP §2163 II.A.1., p. 2100-177, Aug. 2005).

The next step is to determine whether the disclosure satisfies the written description requirement by reviewing the claims and the entire specification (MPEP §2163 II.A.2., p. 2100-177, Aug. 2005). The specification is viewed from the standpoint of the skilled artisan and “should include a determination of the field of the invention and the level of skill and knowledge in the art.” It is well settled that information that is well known in the art need not be described in detail in the specification (MPEP §2163 II.A.2., p. 2100-178, citing *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-1380, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986)). The current specification explains that retinitis pigmentosa (RP) represents a group of hereditary dystrophies characterized by rod degeneration with secondary atrophy of cone

photoreceptors and underlying pigment epithelium (p. 3, lines 13-20). Heredodegenerative diseases are discussed and described in a number of publications cited in the specification. For example, Berson (INVEST. OPHTHALM. VIS. SCI. 34:1659-1676 (1993)) states that dominant forms of RP are found 'on chromosomes 3, 6 and 8; a recessive form on 3; a recessive form with partial deafness called Usher's syndrome, type 2 on 1; and at least two X-linked forms on the short arm of the X-chromosome. Thus, RP is a group of diseases caused by gene abnormalities on several chromosomes." (see p. 1659). Zrenner (Abstracts of the 10th Retina International World Conference in Lugano (Switzerland) p. 41 (1998)) states that "[t]here are hundreds of several diseases which are subsumed under the term 'Retinitis Pigmentosa' which affect vision in a different manner." Therefore, it is submitted that the skilled artisan is well aware of the meaning of the term "heredodegenerative retinal disease" and would understand from the claims and the description in the specification that the inventor is also well aware of the meaning of the term. Thus, it is believed that the inventor was adequately in possession of the claimed subject matter at the time of filing of the application.

In light of the foregoing arguments, Applicant respectfully requests that the rejection based on lack of written description under §112, first paragraph be withdrawn.

C. Conclusion

This is submitted to be a complete response to the outstanding Action. Based on the foregoing arguments, the claims are believed to be in condition for allowance; a notice of allowability is therefore respectfully requested.

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The Examiner is invited to contact the undersigned attorney at (817) 551-4321 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



Teresa J. Schultz
Reg. No. 40,526
Attorney for Applicants

ALCON RESEARCH, LTD.
6201 S. Freeway, Q-148
Fort Worth, TX 76134-2099
(817) 551-4321

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